Remarks

The present invention provides compositions containing second or third generation antidepressants that are not 5-HT_2 receptor antagonists, formulated for local or topical administration. Invention compositions have been shown to produce local analgesia in subjects having a site of local discomfort. Invention formulations possess the advantage of providing a higher and more efficacious concentration of active agent to the region of the sensory nerve terminal than is achievable with systemic administration of the same active agent. In addition, invention compositions for local or topical administration greatly reduce the side effects that may result from systemic administration of antidepressants.

Claims 26, 37-44, 49-53 and 72-83 were pending in the present application prior to the present response. By this response, claims 42, 44 and 49-52 have been amended to define Applicants' invention with greater particularity. These amendments add no new matter as they are fully supported by the specification and original claims. In addition, claims 26 and 72 are cancelled herein without prejudice.

Accordingly, claims 37-44, 49-53 and 73-83 are currently pending. The present status of all claims in the application is provided in the listing of claims presented herein beginning on page 2.

The rejection of claims 37-41, 73 and 79-83 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement because of alleged new matter, is respectfully traversed. The claims have previously been amended to exclude second and third generation antidepressants that are not 5-HT_2 receptor antagonists in invention compositions. Applicants respectfully submit that this limitation is clearly not new matter because it is fully supported by the specification as follows.

For example, the specification describes that "agents which block the uptake of both noradrenaline (NA) and 5-hydroxytryptamine (5-HT) such as amitriptylline, or which **block NA but not 5-HT**, such as desipramine, **are more effective** than those with selectivity for 5-HT, such as fluoxetine" (emphasis added, see specification at page 5, lines 10-13). 5-HT receptors are a class of serotonin receptors, of which 5-HT_2 is a subtype. Furthermore, Example 3 shows that compositions of desipramine (*i.e.*, an antidepressant that is not a 5-HT_2 receptor antagonist) are useful for local administration and pain relief (see, *e.g.*, specification at page 43, lines 18-26). Moreover, the results of Example 4 lead to the conclusion that "it is not shown that 5-HT_2 antagonism accounts for the analgesia demonstrated by amitriptylline and other tricyclic, second generation, or third generation antidepressants observed" (*i.e.*, 5-HT_2 antagonism does not account for the analgesia demonstrated by invention compositions; see specification at page 48, lines 7-9).

Therefore, the exclusion of antidepressants that are 5-HT_2 receptor antagonists in the present claims is fully supported by the specification, and cannot be considered new matter. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection of claims 37-41, 73 and 79-83 under 35 U.S.C. § 112, first paragraph.

The rejection of claims 26, 42-44, 49-53 and 72 under 35 U.S.C. § 102(e), as allegedly being anticipated by U.S. Patent No. 6,290,986 to Murdock *et al.*, is respectfully traversed. However, in order to expedite prosecution, claims 26 and 72 have been cancelled herein, and claims 42-44 and 49-53 have been amended to depend from claim 37. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection of claims 26, 42-44, 49-53 and 72 under 35 U.S.C. § 102(e).

The maintenance of the rejection of claims 37-43, 73, 74, 76, 79 and 81 under 35 U.S.C. § 102(b), as allegedly being anticipated by Amer, U.S. Patent No. 5,266,571 (hereinafter referred to as " '571"), and the rejection of claims 75, 77, 78, 80, 82 and 83 under 35 U.S.C. § 103(a), as allegedly being unpatentable over '571 in view of Knepp *et al., J. Controlled Release* 12:25-30, 1990 (hereinafter referred to as "Knepp"), is respectfully traversed. As

previously submitted, only the present application is directed to second or third generation antidepressant compositions, wherein the antidepressant is not a 5-HT_2 receptor antagonist.

In light of the arguments presented above demonstrating that this claim limitation is fully supported by the specification, '571 cannot anticipate the present claims because it does not disclose the specifically claimed compositions of second or third generation antidepressants. Furthermore, neither '571 nor the Knepp reference, taken individually or in combination, teach or suggest the claimed compositions. Accordingly, Applicants respectfully request reconsideration and withdrawal of both the rejection of claims 37-43, 73, 74, 76, 79 and 81 under 35 U.S.C. § 102(b), and the rejection of claims 75, 77, 78, 80, 82 and 83 under 35 U.S.C. § 103(a).

Conclusion

In view of the above amendments and remarks, prompt and favorable action on all claims is respectfully requested. In the event any matters remain to be resolved in view of this communication, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

Respectfully submitted,

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